MINUTES OF THE 30TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 5-6 DECEMBER 2006 (ADOPTED ON 31 JANUARY 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Ralf Einspanier, Marc De Loose, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi (Vice-Chair), Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal.

EFSA:
GMO Unit: David Carlander, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans, Ellen Van Haver.

PRAPeR Unit: Henning Bruno[1].

European Commission:
Juergen Helbig[1] (DG ENV), Sébastien Goux (DG SANCO) and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Ingolf Nes.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from Ingolf Nes.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. Declarations of interests with regard to applications already announced during previous Plenary meetings are noted in the corresponding minutes. One Panel member[2] has updated his declaration of interest for application EFSA-GMO-NL-2005-24 (40-3-2 soybean for cultivation) as the German Competent Authority was designated for performing the environmental risk assessment of this application (see item 6.2), in which this expert is actively involved. Where Panel members are involved in the initial national assessment of an application for cultivation, these members will not act as rapporteurs on these applications and will abstain from voting on the EFSA opinion.

As regards the new applications GM cotton LLCotton25 x MON 15985 (NL-2006-35) and GM soybean MON 89788 (NL-2006-36), some members[3] indicated that they in the future may be to some extent involved in the safety assessment process of these applications at national level and provided a written declaration. It was decided from these applications that there was no conflict of interest and that the involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 29TH PLENARY MEETING HELD ON 7-8 NOVEMBER 2006

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[1] Only present for the first issue under agenda item 10.
[2] Detlef Bartsch.
[3] Detlef Bartsch and Annette Pöting.

The minutes of the 29th plenary meeting (7-8 November 2006) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_agenda_29th_plenmeet.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Draft report on the use of animal feeding trials for the safety assessment of GM foods/feed

Introduction

The self-tasking activity of the Panel on the use of animal feeding trials for the safety evaluation of *whole* GM foods/feed started its activities in January 2005. The working group had several meetings between January 2005 and October 2006 to come to a finalized version of the document in October 2006.

Discussion and adoption

The draft report was presented to the Panel. The report discusses the various elements of the safety and nutritional assessment approach for genetically modified plant derived foods/feed, in particular the use of animal feeding trials for safety and nutritional testing.

The Panel adopted the draft report 'Safety and Nutritional Assessment of GM Plant derived Foods/Feed - The role of animal feeding trials' for public consultation. The working group and the Panel are seeking scientific views from interested parties, Member States and stakeholders. The draft report will be published on the EFSA website for a 6-week period of public consultation from 15 December 2006 until 31 January 2007 (http://www.efsa.europa.eu/en/science/gmo/gmo_consultations/gmo_AnimalFeedingTrials.html).

5.2. Sugar Beet H7-1 (EFSA-GMO-UK-2004-08 under Regulation 1829/2003)

Introduction

The Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of products produced from the genetically modified sugar beet H7-1 for food and feed uses.

The opinion of the Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The comments from MS that were submitted during the three-month consultation period were addressed individually by the Panel in a separate annex.

The draft opinion and the table with comments from MS were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

The Panel has evaluated information provided on the molecular characteristics of the insert and characteristics of the protein expressed in order to assess the safety of sugar beet H7-1 and its derived products. Further evaluations were focused on agronomic and compositional characteristics, and on nutritional, allergenic and toxicological properties of sugar beet H7-1 and its derived products. The Panel concluded that products from sugar beet H7-1 are safe as food and feed, and, that the nutritional value of the sugar beet H7-1 and the derived sugar beet products is comparable to that of analogous products from conventional sugar beet.

As the scope of this application is for food produced from or containing ingredients produced from sugar beet H7-1 and feed produced from sugar beet H7-1 the Panel considers that there is no requirement for scientific information on environmental risk assessment associated with the accidental release or cultivation of sugar beet H7-1. An environmental monitoring plan for sugar beet H7-1 is not required.

The Panel is of the opinion that based on the outcome of the risk assessment no specific conditions or restrictions for use and handling including post-market monitoring requirements should be imposed for placing on the market products produced from sugar beet H7-1 for food and feed use. Furthermore, there is no need for specific conditions for the protection of particular ecosystems/environment and/or geographical areas.

In conclusion, the Panel considers that information available for sugar beet H7-1 addresses the outstanding questions raised by the Member States and considers it unlikely that sugar beet H7-1 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments can be found on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/gmo_op_ej431_sugar__beet__H7-1.html.

5.3. LLCotton25 (EFSA-GMO-NL-2005-13 under Regulation 1829/2003)

Introduction

The Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of the genetically modified LLCotton25 for import, processing and food/feed uses.

The opinion of the Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The comments from MS that were submitted during the three-month consultation period were addressed individually by the Panel in a separate annex.

The draft opinion and the table with comments from MS were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

LLCotton25 has been modified to express the *bar* gene providing tolerance to glufosinate-containing herbicides. The Panel has evaluated the molecular analysis of the GMO and recognised that only the intended DNA fragment has been integrated at a single locus. From the sequence data provided by the applicant there is no reason to assume that the DNA regions transferred code for toxic and/or allergenic products.

Comparative analysis has shown that the LLCotton25 is compositionally and agronomically equivalent to conventional cotton lines, except for the introduced transgenic trait. The risk assessment included an analysis of data from appropriate animal feeding studies. The Panel concluded that the LLCotton25 is as safe as its non GM counterparts and that the allergenicity of the whole plant is not changed.

The application EFSA-GMO-NL-2005-13 concerns import, processing and food/feed uses. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of LLCotton25. However the Panel is aware that, due to the physical characteristics of cotton seeds and methods of transportation, accidental spillage is unavoidable. Therefore the Panel recommends that, within general surveillance, specific measures are introduced to actively monitor the occurrence of feral cotton plants in areas where seed spillage is likely to occur.

In conclusion, the Panel considers that information available for LLCotton25 addresses the outstanding questions raised by the Member States and considers it unlikely that LLCotton25 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments can be found on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/gmo_op_ej429_LLCotton25.html.

5.4. Guidance document for renewal of authorisations of existing products

Introduction

In accordance with Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003 on genetically modified food and feed, EFSA is requested to publish detailed guidance to assist applicants in the preparation and presentation of the application for renewal of authorisation of GM foods/feed.

The guidance document is applicable for authorisation-holders who have products referred to as existing products, notified according to Articles 8 and 20, which have been published in the Community Register established according to Article 28 of the same regulation. The Community Register can be found at: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm. Applicants

wishing to continue the marketing of their products have to submit an application to the European Commission before 18 April 2007.

Discussion

The 4-page draft guidance document for renewal of authorisations of existing GMO products has been published on the EFSA website (from 17 November to 4 December 2006) for public consultation. Twenty-four comments were received from nine different organisations (national assessment bodies and competent authorities, NGOs and industry associations). The Panel has carefully considered all comments received during this consultation and revised the document accordingly.

Adoption

The guidance document was adopted unanimously by the Panel. The guidance document can be found on the EFSA website at:
http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/ej435_renewal_of_authorisations.html.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

6.1. Past scientific opinions

EFSA received a letter from the Hungarian government in relation to the Hungarian safeguard clause on MON810 (see the minutes of the 28th Plenary meeting[4]). EFSA agreed to hold a meeting with Hungarian experts to discuss the results of an ongoing study that is currently performed in Hungary once this research is completed and the results are fully analysed. The raw data should be made available to EFSA well in advance of a meeting, together with the necessary details related to the material and methods, the statistical analysis and results.

6.2. Ongoing applications

- GA21 maize (Application EFSA-GMO-UK-2005-19; summary: http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/1125.html).
  The Panel has requested additional information on the food/feed safety of GA21 maize. The clock for this application remains stopped.

- 281-24-236 x 3006-210-23 Cotton (Application EFSA/GMO/NL/2005/16; summary: http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/1026.html).
  The applicant informed EFSA that, to provide the Panel with the requested additional information, more compositional data need to be generated. The applicant will therefore only be able to provide the response towards the end of the first quarter of 2008. The assessment of this application will in the meantime be kept on hold.

- 40-3-2 soybean for cultivation (Application EFSA/GMO/NL/2005/24; summary: http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/1243.html).

[4] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_28th_plenmeet.html.

According to Articles 6.3(c) and 18.3(c), the German Competent Authority was designated to carry out an environmental risk assessment of 40-3-2 soybean. In the course of the risk assessment, the German Competent Authority has identified additional questions that require clarification by the applicant. The Panel agrees with the questions to be sent to the applicant. The clock for this application will therefore be stopped.

7. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

7.1. Applications under Regulation (EC) No 1829/2003

EFSA received, via the Netherlands, two new applications (EFSA-GMO-NL-2006-35 and EFSA-GMO-NL-2006-36) within the framework of Regulation (EC) No 1829/2003 for a scientific opinion on GM cotton LLCotton25 x MON 15985 and GM soybean MON 89788 for import and processing, and food and feed use. The summaries can be found at: http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/GMO_NL_2006-35.html and http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/gmo_nl_2006-36.html.

Nominated risk assessment bodies of Member States and National Competent Authorities within the meaning of Directive 2001/18/EC as foreseen in Articles 6 (4) and 18(4) of Regulation 1829/2003 will be consulted by EFSA once the applications are valid. These comments will be considered during the assessment of the applications by the Panel.

8. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. Guidance for the assessment of GM plants used for non-food/feed purposes

A sub-working group meeting was held on 24 November 2006 to discuss toxicity and allergenicity aspects of GM plants used for non-food/feed purposes. The general risk assessment approach for such GM plants was discussed. Furthermore, for each of the hypothetical case-studies, case-by-case aspects of toxicology, allergenicity and compositional analysis were addressed.

9. DATE OF FUTURE MEETINGS

The plenary meeting of March was rescheduled to 22-23 March 2007.

10. ANY OTHER BUSINESS

The Panel drafted a working document in order to define an approach to be followed in the frame of the environmental risk assessment of genetically modified herbicide-tolerant crops associated with the applications of the related herbicides. The aim is to clarify the borderline between the risk assessment of plant protection products and the environmental risk assessment of GMOs. A representative of the PRAPeR Unit and DG ENV were present and were asked to provide their comments on this working document.

The draft document on the risk assessment of plants containing GM events combined by crossing, as well as the comments received through the public consultation[5] will be discussed at the next working group meetings on molecular characterisation, food/feed safety and environmental risk assessment.

The Panel was informed about the final assessment of LLRICE601 carried out by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA). The report is available at: http://www.aphis.usda.gov/brs/aphisdocs/06_23401p_ea.pdf.

[5] See item 12.3 of the minutes of the 26th Plenary meeting (http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/1483.html).